

REMARKS

Prior to this amendment, claims 1-13, 15, 16, 18, 19, 22, 24, and 26-29 were pending. Applicants have cancelled claim 24. Thus, claims 1-13, 15, 16, 18, 19, 22, and 26-29 are currently pending and under consideration.

Applicants have amended claim 16 to recite "in need of such a treatment" in response to the Examiner's rejections.

Applicants have amended claim 19 to correct typographical or grammatical errors.

Applicants have amended claim 26 to depend from pending claim 22 rather than claim 24, which has been cancelled.

None of these amendments add new matter.

Finally, all of these amendments and claim cancellations are specifically without prejudice to applicants seeking patents for the subject matter of the cancelled claims or to the non-elected subject matter.

The Office Action

Rejections under 35 U.S.C. § 112, first paragraph:

Claim 16 stands rejected under 35 U.S.C. § 112, first paragraph, "as failing to comply with the enablement requirement." The Examiner contends that the claimed method involves "inhibiting Aurora-2 activity in any patient that may or may not need the inhibition of Aurora-2" and that such methods are not supported by the specification. Applicants have amended claim 16 to specify that the patients being treated are in need of Aurora inhibition thus obviating this rejection.

Claims 18-19 also stand rejected under 35 U.S.C. § 112, first paragraph "as failing to comply with the enablement requirement." The Examiner contends that the claimed subject matter "was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." According to the Examiner, the claimed methods are directed to the "treatment of cancer generally" (emphasis in original) even though "there never has been a compound capable of treating cancer generally." Applicants traverse.

As would be recognized by skilled practitioners, some compounds may not be capable of treating cancer generally because of their mechanism of action. If a compound's

mechanism of action is specific for a certain type of cancer, then that compound would not be useful for treating cancer generally. However, if a compound's mechanism of action is general for all cell types, then that compound could be used to treat cancer generally.

Applicants' compounds act by a mechanism that is not specific to a certain type of cancer (see, e.g., the specification at page 2, line 24 to page 3, line 3). Applicants' compounds inhibit (among other kinases) Aurora-2 kinase. Aurora-2 kinases are involved in fundamental processes in cell division. Cell division is dependent on the function of Aurora-2 kinase. Aurora-2 activity is therefore essential for cell division. Applicants' compounds, by inhibiting Aurora-2, would inhibit cell division in all types of cells. Therefore, applicants' compounds could be used to treat cancer and, more specifically, the types of cancers recited in claim 19. In another aspect of these rejections, the Examiner contends that the types of cancers recited in claim 19 "are different one from the other." However, as explained above, cancer cells are dependent on Aurora-2 inhibition for division thus linking all the types of cancers. Accordingly, applicants have enabled the treatment of different types of cancers.

Claim 24 stands rejected as lacking enablement. Applicants disagree with the Examiner's rejection. However, to expedite prosecution, applicants have cancelled claim 24.

For all the above reasons, applicants request that the Examiner withdraw these 112, first paragraph rejections.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-13, 15-16, 18-19, 22, 24, and 26-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner contends that the term "heterocyclyl" is indefinite. Applicants traverse.

Applicants respectfully point out to the Examiner that the term "heterocyclyl" is defined in the specification at page 11 starting at line 31 to page 12, line 28. Specifically, the specification in defining the term "heterocyclyl" discloses the following:

The term "heterocycle", "heterocyclyl", or "heterocyclic" as used herein includes non-aromatic ring systems having five to fourteen members, preferably five to ten, in which one or more ring carbons, preferably one to four, are each replaced by a heteroatom such as N, O, or S. Examples of heterocyclic rings include 3-1H-benzimidazol-2-one, (1-substituted)-2-oxo-benzimidazol-3-yl, 2-tetrahydrofuran-3-yl, 3-tetrahydrofuran-2-yl, 2-tetrahydropyran-3-yl, 3-tetrahydropyran-2-yl,

4-tetrahydropyranyl, [1,3]-dioxalanyl, [1,3]-dithiolanyl, [1,3]-dioxanyl, 2-tetrahydrothiophenyl, 3-tetrahydrothiophenyl, 2-morpholinyl, 3-morpholinyl, 4-morpholinyl, 2-thiomorpholinyl, 3-thiomorpholinyl, 4-thiomorpholinyl, 1-pyrrolidinyl, 2-pyrrolidinyl, 3-pyrrolidinyl, 1-piperazinyl, 2-piperazinyl, 1-piperidinyl, 2-piperidinyl, 3-piperidinyl, 4-piperidinyl, 4-thiazolidinyl, diazolonyl, N-substituted diazolonyl, 1-phthalimidinyl, benzoxanyl, benzopyrrolidinyl, benzopiperidinyl, benzoxolanyl, benzothiolanyl, and benzothianyl. Also included within the scope of the term "heterocyclyl" or "heterocyclic", as it is used herein, is a group in which a non-aromatic heteroatom-containing ring is fused to one or more aromatic or non-aromatic rings, such as in an indolinyl, chromanyl, phenanthridinyl, or tetrahydroquinolinyl, where the radical or point of attachment is on the non-aromatic heteroatom-containing ring. The term "heterocycle", "heterocyclyl", or "heterocyclic" whether saturated or partially unsaturated, also refers to rings that are optionally substituted.

Applicants respectfully submit that the above definitions render the term "heterocyclyl" definite and respectfully request that the Examiner withdraw his 112, second paragraph rejections of claim 1 and the claims dependent thereon.

Claim 19 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "cancer of the gastric tract." The Examiner has suggested that applicants amend "gastric" to "gastrointestinal." Applicants have amended claim 19 as suggested by the Examiner thus obviating this rejection.

For all the above reasons, applicants request that the Examiner withdraw these 112, first paragraph rejections.

CONCLUSION

Applicants request that the Examiner enter the above amendments, consider the foregoing remarks, and allow the pending claims to issue. If the Examiner believes that a telephone call would expedite prosecution, the Examiner is invited to contact the undersigned at any time.

Respectfully submitted,



Lisa A. Dixon
Registration No: 40,995
Attorney for Applicants
VERTEX PHARMACEUTICALS INCORPORATED
130 Waverly Street
Cambridge, Massachusetts 02130-4646
Tel: (617) 444-6396
Fax: (617) 444-6483

7135_1